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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,655

08/16/2005

Sitke Aygen

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6168

136 7590 09/15/2009

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

09/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,655	<b>Applicant(s)</b> AYGEN, SITKE	
	<b>Examiner</b> PATRICIA C. MALLARI	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/09 has been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "the release of  $^{13}\text{CO}_2$  in the exhaled air of the subject before . . . intravenous administration of secretin and before . . . the oral administration of the  $^{13}\text{C}$ -triglyceride to the subject". There is insufficient antecedent basis for this limitation in the claim. In addition, the first step of the claim recites that the release of  $^{13}\text{CO}_2$  is induced by administration of secretin and  $^{13}\text{C}$ -triglyceride to the subject. If the administration of these substances induces the release of  $^{13}\text{CO}_2$ , then it is also unclear how the release of  $^{13}\text{CO}_2$  can be measured before the administration of

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these substances since the release of  $^{13}\text{CO}_2$  is not induced until administration of the substances occur. The applicants should clarify.

Claim 17 recites the limitation "measuring the induced value of  $^{13}\text{CO}_2$  in the exhaled air of the subject before . . . intravenous administration of secretin and before . . . oral administration of the  $^{13}\text{C}$ -triglyceride to the subject". There is insufficient antecedent basis for this limitation in the claim. Furthermore, the first step of the claimed method states that administration of secretin and  $^{13}\text{C}$ -triglyceride induces the release of  $^{13}\text{CO}_2$ . If the administration of these substances induce the release of  $^{13}\text{CO}_2$ , it is unclear how an "induced value of  $^{13}\text{CO}_2$ " could be released before administration of these substances since no induction occurs before administration of the substances. The applicants should clarify.

Claim 17 recites "comparing (i) the measured induced value of  $^{13}\text{CO}_2$  in exhaled air of the subject". It is unclear whether this limitation refers to the value measured before intravenous administration of secretin, after intravenous administration of secretin, before oral administration of the  $^{13}\text{C}$ -triglyceride, or after oral administration of the  $^{13}\text{C}$ -triglyceride. The applicants should clarify.

Claim 17 recites "an induced value of  $^{13}\text{CO}_2$ ". It is unclear whether this value is the same as or different from "the induced value of  $^{13}\text{CO}_2$ " recited earlier in the claim. The applicants should clarify.

***Allowable Subject Matter***

Claims 12-21 would be allowable if claims 12 and 17 were rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. The allowability of claims 12-16 was addressed in the previous Office action filed 9/9/08 and is repeated below.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 12-21, the primary reason for allowance is the inclusion of measuring the release of  $^{13}\text{CO}_2$  in the exhaled air of the subject before and after intravenous administration of secretin, in combination with all of the other limitations of the claims, which is not taught or fairly suggested by the prior art of record.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/  
Primary Examiner, Art Unit 3735